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09/779,693	02/07/2001	Jonathan B. Rothbard	19801-000110US	6760

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EXAMINER
JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
1616	8

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/779,693	Applicant(s) ROTHBARD ET AL.	
	Examiner D. L. Jones	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2001 and 10 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,33 and 40* is/are rejected.

7)☒ Claim(s) *34-39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) P
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 1 ½ filed 2/7/01, wherein the specification was amended.

Note: Claims 1-40 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to a compositions and methods thereof comprising a biologically active agent, a delivery-enhancing transporter, and a pharmaceutically acceptable carrier.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election with traverse of Group II (claims 32-40) in Paper No. 7, filed 3/10/03, is acknowledged. In addition, the Examiner acknowledges the election of the species wherein taxol is the biological agent and the transporter is a peptide containing exactly seven L-arginine members. It is noted that Applicant has traverse the election of species requirement on the ground that no undue burden exists to search and examine all of the claimed compounds. This is found non-persuasive because it should be noted that the Examiner asked Applicant to elect a species for search purposes. Thus, the Examiner was respectfully requesting that Applicant give a starting point for the search. It is duly noted that Applicant did not traverse the restriction into groups and elected Group II for prosecution. Hence, the restriction requirement is still deemed proper and is therefore made FINAL.

Note: Initially, the Examiner searched for Applicant's elected species. However, since no prior art could be found to reject Applicant's elected species, the search was expanded over the full scope of Group II.

WITHDRAWN CLAIMS

4. Claims 1-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

DOUBLE PATENTING REJECTIONS

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 32 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 30 of copending Application No. 09/957,161. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising a biologically active agent, transporter agent, and a pharmaceutically acceptable carrier. The claims differ in that the claims of 09/957,161 list specific ranges of guanidine or amidino moieties required for the (transporter agent).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claim 32 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 09/083,259. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising a biologically active agent, transporter agent, and a pharmaceutically acceptable carrier. The claims differ in that the claims of 09/083,259 list specific ranges of guanidine or amidino moieties required for the transport peptide and the biologically active agent is paclitaxel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claim 32 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 18 of copending Application No. 09/396,195. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising a biologically active agent and transporter agent. The claims differ in that the claims of 09/396,195 list specific ranges of guanidine or amidino moieties required for the transport peptide and the peptide is linker to the antimicrobial agent (biologically active agent).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 REJECTIONS

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 32 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32, line 3: The claim as written is confusing because it is unclear what Applicant intends by the phrase 'sufficient guanidine or amidino moieties'. Specifically, what does Applicant consider to be the desired amount? Please clarify.

Claim 40 as written is ambiguous because it is unclear whether Applicant intended the claim to read upon 33 or 32. In particular, claim 32 discloses the transporter agent. Applicant is respectfully requested to clarify the record in order that one may readily ascertain what is being claimed.

102 REJECTION

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 32 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Sumner-Smith et al (CA 2,094,658).

Sumner-Smith et al disclose the intracellular delivery of biochemical agents (e.g. peptides and oligonucleotides) which is facilitated by a coupled carrier peptide preferably consisting of eight or nine arginine residues (see entire document, especially, abstract and pages 13-14, claims 1-6 and 12). In addition, Sumner-Smith et al disclose Example 1 (page 9) which details the synthesis of acetyl-[D-Arg]9-NH2 which during synthesis contains a protected guanidine moiety. A carbon-14 peptide of Example 1 was produced and analyzed for evidence of uptake in subject as set forth on page 11 of

the reference (see pages 10-11). Example 3 (page 12) discloses the distribution of the carbon-14 labeled peptide in vivo.

Thus, both Sumner-Smith et al and Applicant disclose a composition comprising a biologically active agent, a delivery-enhancing transporter have guanidine/amidino moieties, and a pharmaceutically acceptable carrier.

103 REJECTION

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 32, 33, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al (US Patent No. 6,005,004).

Katz et al disclose a delivery system comprising a biologically active agent, a transporter agent, and a pharmaceutically acceptable carrier (see entire document, especially, abstract). In addition, Katz et al disclose that the complex may optionally comprise a polyamino acid such as polyarginine or polyornithine (column 6, lines 27-35) to facilitate crossing of the blood-brain barrier. Katz et al do not disclose an embodiment comprising all of the Applicant's components in an example; however, the reference does suggest a composition containing the various components as claimed by Applicant's invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Katz et al and generate a composition comprising a biologically active agent, a delivery transporter contain guanidino/amidino moieties, and a pharmaceutical carrier because Katz et al disclose a delivery system comprising a biologically active molecule that is further covalently bonded to a carrier and peptide for delivery across the blood-brain barrier. Furthermore, is should be noted that a skilled practitioner in the art using a standard chemical dictionary (e.g., a chemical dictionary) would realize that both polyarginine and polyornithine contain guanidino/amidino residues.

CLAIM OBJECTIONS

15. Claims 34-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the specific biologically active agents in combination with the limitations of intervening claims.

COMMENTS/NOTES

16. Applicant is respectfully requested to cancel the claims directed to the non-elected subject matter.

17. Applicant is respectfully requested to supply the inventor(s) name(s) for document JP 100095738 (document X) listed on the information disclosure statement filed 3/25/02. In addition, Applicant is respectfully requested to submit the year of the Sigma Catalog listed on the information disclosure statement (document BP).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

May 27, 2003